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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/206,249 12/07/98 SEIBERG

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HM22/0907

EXAMINER

MELLER, M

ART UNIT	PAPER NUMBER
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1651

13

DATE MAILED:

09/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/206,249

Applicant(s)

SEIBERG ET AL.

Examiner

Michael V. Meller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 1, 3, 5-7, 23, 25-27, 37, 39, 41-43, 48-57, 59-69, parts of 72 pertaining to serine protease inhibitors and 73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 4, 8-22, 24, 28-36, 38, 40, 44-47, 58, 70-72 and 74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

DETAILED ACTION

Election/Restrictions

This application contains claims 1, 3, 5-7, 23, 25-27, 37, 39, 41-43, 48-57, 59-69, 72 (with respect to the agent being a serine protease inhibitor) and claim 73 are drawn to an invention non elected with traverse in Paper No. 12. A complete reply to the final rejection must include cancellation of non elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 2, 4, 8-21, 24, 28-35, 38, 40 and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Limtrakul et al.

Applicant argues that Limtrakul does not teach administration of the soybean milk to humans, but the claims do not require a human, only a mammal which a mouse is.

Applicant argues that Limtrakul teaches that there have been reports on the unfavorable effects of soybean trypsin inhibitor for health. First of all, the claims are directed to the use of soybean milk not a soybean trypsin inhibitor. Second, Limtrakul

was only reporting (by way of his background) that this inhibitor has been reported by some to have unfavorable effects for health. If one were to read the last sentence of that same paragraph, one would find that the paper also states that other researchers have reported that such effects cannot be observed even with relatively high amount of trypsin inhibitor in man, monkey, dog, etc., see page 1592, first paragraph.

Next applicant argues that Limtrakul does not teach the application of soybean milk topically. The fact of the matter is, the above claims do not stipulate how the soybean milk is to be administered, thus the argument is moot.

Next, applicant argues that STI compounds are destroyed by processing soybean derivatives, such as by heating. Applicant states that this process inactivates the STI compounds and that the instantly claimed process does not inactivate the STI components. Fact is, no where in the reference can such a claim be found. Applicant is asked to cite page and line for the examiner. The reference never heats the compounds. Further, the soybean milk is what is being administered to the animal. The compounds may be in the milk but it is the milk that is being administered as is done in applicant's process.

Claims 2, 4, 8-22, 24, 28-36, 38, 40 and 44-47 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Kosaka.

Applicant argues that Kosaka requires the addition of papain and citric acid administered orally. Applicant's state that since papain is a serine protease it would not make sense to include it in a composition with a serine protease inhibitor. While this is

an interesting point, applicants elected soybean milk which is taught by the reference and which anticipates applicant's claims.

Claims 2, 4, 8-22, 24, 28-36, 38, 40 and 44-47, 58 and 70-74 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 62036304 (304).

Applicant argues that 304 merely refers to the use of soybean milk as a cosmetic for skin and hair or for "conditioning". They also argue that 304 nowhere recognizes the necessity of maintaining the presence of nondenatured STI components in soymilk compositions nor the use of soymilk containing nondenatured STI components for affecting phagocytosis. 304 does teach the agent, soybean milk and does teach that it is applied topically. The composition of 304 is never heated thus it is not denatured. Thus, applicants comments are not well taken. The composition and method are clearly anticipated by 304.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA § 102(e)).

Claims 2, 4, 8-22, 24, 28-36, 38, 40, 44-47, 58 and 70-74 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No.

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09/110,409 which discloses the composition of soybean milk and a cosmetically acceptable carrier/vehicle and discloses a method of using the composition which inherently will decrease phagocytosis or ICAM-1 expression in a mammalian cell as in the instant application.

Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future patenting of the copending application.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

Applicants comments are noted but the two applications are both administering the same composition to a mammal.

Claim Rejections - 35 USC § 103

Claims 2, 4, 8-22, 24, 28-36, 38, 40, 44-47 and 58 are rejected under 35 USC 103(a) as being unpatenable over Limtrakul et al. taken with Kosaka or JP 62036304 (304).

The arguments of applicant are discussed above. The references still render the claimed invention obvious to one of ordinary skill in the art for the cited reasons of record. Note that 304 teaches administering the composition to the skin.

Claims 70-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Limtrakul et al or Kosaka taken with JP 62036304 (304).

The teachings of Limtrakul and Kosaka are of record. They do not teach administering the soybean milk topically.

304 teaches to beneficially topically administer soybean milk.

Thus, it would have been obvious to administer soybean milk topically in the process of Limtrakul or Kosaka, since 304 teaches that soybean milk can beneficially be administered topically.

Double Patenting

Claims 2, 4 and 8-22 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 60 of copending application, 09/110,409. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Applicants comments are noted but the compositions are the same in both applications. Thus, the rejection is maintained.

Claims 2, 4, 8-22, 24, 28-36, 38, 40, 44-47, 58 and 70-74 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-60 of copending Application No. 09/110,409.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants comments are noted but the rejection is maintained for the reasons of record and since the claimed composition is obvious over the cited application.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 10:30am-7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

MVM
September 5, 2001


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651